IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 4:21-cv-10312-FKB-RSW

Hon. F. Kay Behm

MOTION FOR PARTIAL SUMMARY JUDGMENT

DECLARING THAT U.S. PATENT NO. 8,163,802 IS VALID

Pursuant to Fed. R. Civ. P. 56, Plaintiff/Counter-Defendant, Trutek Corp. ("Trutek"), by and through its undersigned counsel, Stanley H. Kremen and Keith Altman, respectfully moves for summary judgment of validity of U.S. Patent 8,163,802 ("the '802 Patent"). The stipulated order entered January 23, 2023 extended the page limits for briefs in support of despositive motions to 40 pages. ECF 55; *see also* Text-Only Order dated February 7, 2023.

On January 17, 2023, counsel for the parties met and conferred. Trutek's counsel explained to counsel for Defendant/Counter-Plaintiff, BlueWillow Biologics, Inc. ("BlueWillow"), that Plaintiff would be filing a motion for partial summary judgment for patent validity and a motion to exclude testimony of BlueWillow's expert, Mansoor M. Amiji. BlueWillow's counsel indicated that Defendant would oppose both motions.

Summary judgment on the issue of patent validity is proper because all of the material facts required to make a judgment as a matter of law are already known.

First, the '802 Patent is presumed valid. While the patented technology is involved, the determination of patent invalidity is legal in nature, and must be demonstrated by the Defendant by clear and convincing evidence. BlueWillow failed to meet its burden of proof.

Second, both fact and expert discovery is closed. BlueWillow engaged only one expert witness, Dr. Mansoor M. Amiji. On June 27, 2022, Dr. Amiji submitted his opening expert report (ECF 56-2), in which he presented his opinions on invalidity of the '802 Patent. Virtually, all of the opinions expressed by Dr. Amiji are legal in nature. Dr. Amiji is neither an attorney nor is he licensed to practice before the USPTO. He said that the law and principles thereof was explained to him by counsel. Dr. Amiji did not perform his own research to locate prior patent references to show invalidity. Instead, his opinions merely ratified the opinions of counsel who provided him with the references. In his report, Dr. Amiji opined that the claims of the '802 Patent that were at issue are invalid based on patent statutes, 35 U.S.C. §§ 101, 112, 102, and 103. However, in his report, he demonstrated that he neither understood the law nor did he understand or follow the correct procedures to show patent invalidity. In many instances, he invented his own legal standards, which were incorrect. Dr. Amiji put forth his opinions both in his report and in his deposition taken on October 14, 2022. In his deposition testimony, Dr. Amiji stated that the opinions expressed in his reports represent all of the opinions held by him as of the date of his deposition..

Faced with the incorrect legal opinions presented by Dr. Amiji, Plaintiff had no alternative but to rebut his legal opinions and the procedures that he followed as well as whatever few scientific conclusions presented by him. To do this, Plaintiff engaged the services of Amirali Y. Haidri, Esq., who is a patent attorney with expertise in organic chemistry and chemical engineering, and who is familiar with the '802 Patent and its technology from prior experience. On August 12, 2022, Mr. Haidri presented his expert report responsive to Dr. Amiji's opening report on invalidity. Where Dr. Amiji's interpretation of the law was incorrect, Mr. Haidri showed this to be the case. To prove his points, Mr. Haidri cited patent statutes and judicial precedent. However, where Dr. Amiji applied erroneous procedures or misunderstood the technology, Mr. Haidri provided rebuttal testimony.

In addition, Trutek presented an expert report from Dr. Edward Lemmo, who's expertise lies in the development of products similar to those derived from the technology of the '802 Patent. Dr. Lemmo's opinions were in rebuttal to Dr. Amiji's technical opinions.

Third, in Dr. Amiji's reports and deposition testimony, he opined on the qualifications of the person having ordinary skill in the art ("PHOSITA")[1]. Dr. Amiji's PHOSITA was required to have at least a

[1] PHOSITA is a standard acronym meaning **P**erson **H**aving **O**rdinary **S**kill **I**n **T**he **A**rt.

masters degree in chemical engineering or pharmaceutical sciences plus extensive experience as part of a multi-disciplinary team. At the Markman hearing held on November 15, 2022, this Court rejected Dr. Amiji's definition, and instead adopted Plaintiff's definition. Selecting the correct definition of a PHOSITA is critical to determinations of enablement under 35 U.S.C. § 112 and obviousness under 35 U.S.C. § 103. Further, Dr. Amiji used his definition of PHOSITA in other opinions, even when such use was not correct. In his deposition, Dr. Amiji stated that he considered himself to be a PHOSITA. Actually, he is a person having **extraordinary** skill. Thus, although he was required to view enablement and obviousness (along with other facts) from the viewpoint of an actual PHOSITA (as accepted by this Court), Dr. Amiji viewed these facts through his own lens. This is impermissible.

Finally, the '802 Patent is presumed to be valid. Unless the Defendant can show invalidity by clear and convincing evidence, validity of the patent must be affirmed. Discovery is complete, and all opinions have already been rendered. Defendant failed to prove invalidity by a clear and convincing evidentiary standard. This Court should grant Plaintiff's motion for partial summary judgment on validity, and declare that the '802 Patent is valid.

For the reasons stated in the accompanying brief in support, the Court should grant Trutek's Motion for Partial Summary Judgment.

Dated: __March 29, 2023__

Respectfully submitted,

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TRUTEK'S BRIEF IN SUPPORT FOR PARTIAL SUMMARY JUDGMENT

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I. INTRODUCTION

Plaintiff, Trutek Corp. ("Trutek") respectfully submits that summary judgment should be granted in favor of validity of claims 1, 2, 6, and 7 of U.S. Patent No. 8,163,802 B2 ("the '802 Patent"). The '802 Patent is presumed valid under 35 U.S.C. § 282(a). While this presumption is rebuttable, it is the Defendant's burden to prove invalidity of the claims at issue by a clear and convincing evidence standard. *Microsoft Corp. v. i4i Limited Partnership,* 564 U.S. 91 (2011). Defendant failed to meet its burden to establish invalidity of the claims by clear and convincing evidence. Therefore, Plaintiff's motion for summary judgment should be granted.

II. BACKGROUND

This lawsuit was filed by Plaintiff Trutek against Defendant BlueWillow Biologics, Inc. ("BlueWillow") on February 10, 2021. Trutek owns several patents, which form the basis for products that it sells. Trutek's products are marketed under several trademarked brand names, among them being NasalGuard®. The technology of the NasalGuard® products derive from the Trutek patents. The '802 Patent is one of these. The NasalGuard® products sold in the United States all have Trutek's patent numbers (including that of the '802 Patent) clearly marked on their packaging.

Exhibit 3 shows packaging images of Trutek's compliance with the Marking Statute, 35 U.S.C. § 287.

The NasalGuard® formulations work by creating a positive electrostatic field in and around a person's nasal cavities. When applied to a person's nose, the NasalGuard® product attracts negatively charged harmful particles (*e.g.,* germs, bacteria, viruses, *etc.*), holds them in place (preventing them from being inhaled by the respiratory system), and a biocide in the formulation inactivates the harmful particles. This combined action can be referred to as CATCH, HOLD, and KILL.

In the year 2020, Defendant BlueWillow began selling a product branded Nanobio® Protect. This product was advertised and sold online on the same websites as Trutek's NasalGuard® product. Trutek personnel suspected the the Nanobio product infringed the '802 Patent. BlueWillow's website depicted that this product, when applied to the nasal cavities, forms nanodroplets that establishes a positive electrostatic field in the nose. The positively charged nanodroplets attract negatively charged germs, and surround them. A biocide then kills the germs. The biocide used in the Nanobio product was benzalkonium chloride. Claim 7 of the '802 Patent recites the use of this biocide.

Trutek performed in-house testing, which was later verified by outside laboratories. It was determined from testing that the electrostatic fields were of the same order of magnitude for the BlueWillow product as they were for the Trutek product. Beyond this, Trutek relied on BlueWillow's own statements on its website to confirm that infringement occurred.

Several months after the present lawsuit was filed, BlueWillow removed the Nanobio® Protect product from the market.

Very little fact discovery took place. Discovery centered around experts. On June 27, 2022, Dr. Mansoor M. Amiji submitted an opening expert report on patent invalidity (ECF 56-2). Dr. Amiji is a licensed pharmacist in Massachusetts, and a professor of pharmaceutical sciences and chemical engineering at Northeastern University in Boston. As will be shown, the opinions expressed in Dr. Amiji's report are mostly legal in nature. They involved parsing the various patent statutes and using procedures similar to those used by USPTO patent examiners, albeit incorrectly. Dr. Amiji misinterpreted the patent statutes. He repeatedly stated that he is not an attorney, and that he was informed of the law by counsel. In his deposition, he stated that he did not do his own research into the prior art, and that the patent references that he used were provided to him by counsel Dr. Amiji's deposition was previously uploaded as ECF 61-3.

In order to rebut Dr. Amiji's opinions, on August 15, 2022, Amirali Y. Haidri, Esq. submitted a responsive expert report (previously uploaded as ECF 56-3) in rebuttal of Dr. Amiji's opinions expressed in his report. Mr. Haidri is a patent attorney with a B.S. in chemical engineering and an M.S. in organic chemistry. Mr. Haidri is licensed to practice at the USPTO, and he has written and prosecuted patents since 1982. He is very familiar with the technology of the '802 Patent since 2018 based on his education and experience and the fact that he represented Trutek in a previous patent infringement lawsuit against another company. That lawsuit settled favorably for Trutek. See Decl. Amiraly Y. Haidri as Exhibit 2, herewith.

Dr. Amiji's opinions were mostly legal in nature, and he cited patent statutes, which he misinterpreted. Where he did so, Mr. Haidri had no alternative but to rebut his opinions with correct legal reasoning and precedent. Where Dr. Amiji used the wrong procedures and standards to examine the claims of the '802 Patent, Mr. Haidri had no alternative but to rebut with the correct procedures. Where Dr. Amiji misstated the technology, Mr. Haidri had no alternative but to state correct science.

On August 22, 2022, Dr. Edward A. Lemmo submitted an expert report responsive to Dr. Amiji's opening report (ECF 56-2). Dr. Lemmo's report is presented herewith as Exhibit 4. Dr. Lemmo has vast experience in

development of over-the-counter products similar to those at issue in this lawsuit and marketed by Trutek and BlueWillow. Dr. Lemmo was asked to opine on four issues:

1. the level of skill required by a person having ordinary skill in the art ("PHOSITA") related to the claims of the '802 Patent;
2. the scientific and technical aspects of the 'hold" function recited in Elements (b) in claims 1 and 2 of the '802 Patent and why the "hold" function is critical to the patented invention;
3. enablement of the disclosure contained in U.S. Patent Publication No. 2004/0071757 A1 by David Rolf; and
4. relevance of the commercial success of Trutek's products to nonobviousness of the claims of the '802 Patent.

On October 14, 2022, deposition testimony was taken from Dr. Amiji.

III. LEGAL ARGUMENT

According to 35 U.S.C. § 282(a), patents are presumed to be valid. In order to show invalidity, the Defendant bears the burden of proof by a clear and convincing evidence standard. *Microsoft Corp. v. i4i Limited Partnership,* 564 U.S. 91 (2011). BlueWillow failed to meet this burden. Defendant presented opinions that were incorrect, where he misinterpreted

the statutes 35 U.S.C. §§ 101, 102, 112, and 103 and their associated procedures.

"'Clear and convincing evidence' is that weight of proof which produces in mind of trier of fact a firm belief or conviction as to truth of the allegations sought to be established; it is evidence so clear, direct, weighty and convincing as to enable fact-finder to come to clear conviction, without hesitancy, of truth of the precise facts of case." *In re CNC Payroll, Inc.*, 491 B.R. 454, 461 (2013), citing *Shafer v. Army & Air Force Exch. Serv.,* 376 F.3d 386, 396 (5th Cir.2004). See also, *In re JMW Auto Sales*, 494 B.R. 877, 889 (2013).

A. THE PERSON HAVING ORDINARY SKILL IN THE ART

Under 35 U.S.C. § 112, the determination of enablement necessitates the understanding of a PHOSITA. This person having ordinary skill is a fictitious person who is a technician, but who also has knowledge of all prior art in his field. This person must have the ability to make and use the claimed invention using the written description as a guide. However, the patent does not need to be a manufacturing specification. The PHOSITA is expected to perform experimentation provided that such experimentation is not undue. Further, the determination of obviousness of a claim under 35 U.S.C. § 103 requires one to look to the claimed invention through the lens

of a PHOSITA at the time that the application was filed. If the wrong PHOSITA is chosen, determination of enablement and obviousness is meaningless. Incorrect determination of the qualifications of a PHOSITA has resulted in reversible error. *Custom Accessories, Inc. v. Jeffrey-Allen Indus., Inc.,* 807 F.2d 955 (Fed. Cir. 1986).

Dr. Amiji opined that a PHOSITA must have attained "at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation." (ECF 56-2, pg. 28, ¶68.) However, this Court disagreed with Dr. Amiji, and adopted Plaintiff's definition of a PHOSITA. (ECF 53, pp. 2 and 10. See also Court's discussion *Id.,* at pp. 8-10.) The definition put forth by Plaintiff is:

> *The person of ordinary skill would not have read the '802 Patent stand-alone. Based on his knowledge and experience, this person would be familiar with all the ingredients listed in the ten formulations shown in the '802 Patent. He would have the skill and experience to duplicate those formulations once having seen their list of ingredients. He must know enough chemistry and biology to be familiar with cationic agents and biocidic agents. He must have knowledge of the various airborne "harmful particles," such as bacteria, viruses, pollen, and other allergens. He must know enough undergraduate physics to understand electrostatic fields as well as the principles of electrostatic attraction and repulsion, adhesion, and cohesion. to that end, he needs familiarity with ingredients that are surfactants, thickeners, and binders.*
> (ECF 40, pg. 12.)

In his deposition, Dr. Amiji testified that he considers himself to be a PHOSITA. (Depo. Amiji, 81:22 - 82:8.) *See* ECF 61-3. However, Dr. Amiji is a person having extraordinary skill in the art. By viewing the issues of claim construction, enablement, and obviousness through the lens of an incorrect PHOSITA, and imagining himself as that PHOSITA, his opinions were viewed improperly through his own lens. This is not a trivial error.

B. DR. AMIJI'S OPINIONS REGARDING 35 U.S.C. § 101

35 U.S.C. § 101 states, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

1. SUBJECT MATTER ELIGIBILITY

In Dr. Amiji's first opinion regarding this statute, he stated that the claims at issue "are invalid for being directed to ineligible subject mater under 35 U.S.C. § 101." (ECF 56-2, pg. 95, § XII.) Here, Dr. Amiji misinterpreted the statute and law regarding subject matter eligibility. First, he ignored the first basic inquiry for subject matter eligibility where claim 1 is directed to a method (*i.e.,* a process), and claims 2, 6, and 7 are directed to a formulation (*i.e.,* a composition of matter). Instead, he only addressed the second inquiry to determine whether the invention's claims wholly embrace

non-man-made judicial exceptions to patentability, *e.g.,* laws of nature, physical phenomena, and abstract ideas, or conversely whether "it is a particular practical application of a judicial exception." *Diamond v. Chakrabarty,* 447 U.S. 303, 309 (1980). *See also* MPEP § 2106(II).

Dr. Amiji discussed the law regarding these judicial exceptions to patentability, but he ignored whether the claims at issue represent "a particular practical application of a judicial exception. (ECF 56-2, pp. 18-19, ¶¶ 42-43.) Then, under a heading of Subject Matter Eligibility, he states his opinion as, "XII. Analysis: Claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101." (*Id.* pg. 95.) He states:

> *The '802 Patent is directed to the effects of a law of nature or a natural phenomena, namely the principle that like charges repel each other, while unlike charges attract, e.g., a positive charge attracts a negative charge. While the Challenged Claims of the '802 patent recite additional elements, each of those additional claim elements are either conventional steps that are well known to a POSA*[1] *or depend on the very same law of nature or natural phenomena. Thus, in my opinion, the '802 Patent claims do not recite any inventive concept that would transform the law of nature into a patent eligible invention.*
> (*Id.* at ¶ 202.)

[1] POSA (**P**erson of **O**rdinary **S**kill in the **A**rt) is Dr. Amiji's acronym instead of the more common acronym PHOSITA (**P**erson **H**aving **O**rdinary **S**kill **I**n **T**he **A**rt).

Pages 31 through 46 of Dr. Amiji's deposition taken on October 14, 2022 deal with Dr. Amiji's understanding of subject matter eligibility under 35 U.S.C. § 101.

In his deposition, Dr. Amiji was asked, "You express an opinion about the statute of 35 USC 101, what is 101?" (Depo. Amiji, 31:22.) Defense Counsel objected to the question stating that he is not a legal expert. (*Id* at 32:9-14.)

When pressed further, Dr. Amiji stated, "**...** my understanding of the patent law is what was provided to me. and then subsequent to that, I have discussed the various parts of those standards." (*Id.* at 33:14-20.) Regarding the first inquiry under 35 U.S.C. § 101, Dr. Amiji admitted, after repeated questioning, that claim 1 recites a process and that claim 2 recites a composition of matter. However, he still maintained that the claims contained ineligible subject matter (*viz.,* electrostatic attraction) and that he made that determination through the lens of a PHOSITA. He said, "**...** I'm not a lawyer, but as I read the claims, and in view of a personal [*sic.*] skill in the art,[2] **...** " (*Id.* 35:6-7) He further said, "[m]y understanding is that for subject mater to be patentable, there has to be some novelty beyond what is

[2] The Deponent actually said, "person of skill in the art."

well known to personal [*sic.*] skill in the art as occurring by nature." (*Id.* at 38:9-12.) This is not the proper standard of review.

First, a PHOSITA is never mentioned in the Statute. 35 U.S.C. § 101 requires an objective determination. Dr. Amiji applied the facts to an incorrect interpretation of the statute.

In the first inquiry of §101, if a claim falls objectively into one of the four stated categories, the subject matter is eligible for patentability. Dr. Amiji ignored this first inquiry. Instead he concentrated on the second inquiry, which arises from the objective fact that one cannot patent a non-man made discovery such as a law of nature, a physical phenomenon, or an abstract idea.

However, all inventions utilize laws of nature in some way. While Albert Einstein could not patent his famous law equating mass and energy, $E=mc^2$, an inventor may patent a nuclear reactor that uses that law. None of the claims at issue in the '802 patent claim electrostatic attraction. However, the claims all utilize this law of nature. The claimed formulations (*i.e.,* claims 2, 6, and 7) contain a cationic agent[3] as but one of its ingredients. And, process claim 1 recites "electrostatically attracting" as but one of its steps. From Dr. Amiji's testimony, it is difficult to ascertain whether he

[3] A cationic agent is an ingredient that exhibits a positive electrostatic charge.

realizes that an invention may utilize a law of nature in one or more of its elements and still be patentable. In his report, Dr. Amiji states:

> *While the Challenged Claims of the '802 patent recite additional elements, each of those additional claim elements are either conventional steps that are well known to a POSA, or depend on the very same law of nature or natural phenomena.* (ECF 56-2, pg. 95, ¶202.)

Other than the fact that the claims recite additional elements, the above statement is untrue. However, the issue here is that this viewpoint is not the proper standard for a §101 inquiry into subject matter eligibility.

Subject matter eligibility under 35 U.S.C. § 101 is a legal issue, and while defense counsel may have informed Dr. Amiji of certain standards, it is clear that (1) he does not know the meaning of the statute regarding subject matter eligibility; (2) he used the wrong standards to determine whether the claims contain eligible subject matter; and (3) he is not qualified as an expert to testify on these matters.

2. CREDIBLE UTILITY

In his report, Dr. Amiji opined that the claims at issue "are invalid under 35 U.S.C. §§ 101/112 for lack of credible utility." (ECF 56-2, pg. 99, ¶212.) 35 U.S.C. §101 requires that a patentable invention be new and useful. Credible utility is a definite requirement of 35 U.S.C. § 101. If an

invention is not useful, no patent may issue. However, there is no such requirement usefulness within any of the six provisions of 35 U.S.C. § 112.

The specification of the '802 Patent discloses ten different formulation embodiments in which the ingredients are listed in percent ranges by weight. According to the inventor, all of the formulation embodiments function effectively as described in the disclosure. However, in Dr. Amiji's report, he states that unless data or test results are provided in the specification, a PHOSITA would be unable to determine whether the formulations listed would work as described. (ECF 56-2, pp. 99-100, ¶214.)

While inclusion of test data and testing protocols are sometimes provided in patent specifications, this is not a requirement either under 35 U.S.C. § 101 or § 112. As argued *supra*, 35 U.S.C. § 101 makes no mention of a PHOSITA. Further, 35 U.S.C. § 112 makes no mention of credible utility. Dr. Amiji is confusing this with the enablement requirement of §112(a) or pre-AIA § 112, first paragraph. That enablement requirement will be addressed *infra*.

At his deposition, Dr. Amiji was asked whether a formulation that actually inhibits infection due to inhalation of harmful particles is useful. In response, he said that, "the teaching of the 802 would be useful, but it's not." (Depo. Amiji, 47:13.) When questioned whether it is true "that no statute or

rule specifically required such data or test results for patentability," he responded, "[m]y opinion is that the 802 patent doesn't teach to a personal [*sic.*] skill in the art specific composition that enables the claim." (*Id.* at 47:21 - 48:4.)

It should be clear at this point that Dr. Amiji presented opinions of a legal nature regarding 35 U.S.C. § 101, and that he misinterpreted the requirements of the statute. Effectively, Dr. Amiji created his own criteria of determining subject matter patent eligibility and credible utility that do not comport with existing law. His opinions are "made up." "Nothing in either *Daubert*[4] or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *General Elec. Co. v. Joiner*, 522 U.S. 136, 137 (1997).

C. DR. AMIJI'S OPINIONS REGARDING 35 U.S.C. § 112

The first paragraph of pre-AIA[5] 35 U.S.C. § 112 reads as follows:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set*

[4] *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

[5] "AIA" is an acronym for the America Invents Act, enacted into law by the 112th Congress on September 16, 2011.

> *forth the best mode contemplated by the inventor of carrying out his invention.*
>
> Currently, 35 U.S.C. § 112(a) reads as follows:
>
> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.*

Because the '802 Patent is based upon a patent application filed in 2009, and the patent issued in 2012, there is some debate as to which statute should apply. However, the §112 paragraphs above apply equally when evaluating the '802 Patent. As can be observed, § 112(a) or pre-AIA § 112, first paragraph has three requirements:

- to provide a written description of the invention (*i.e.*, the **Written Description** requirement);
- "to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same" (*i.e.,* the **Enablement** requirement); and
- shall set forth the best mode contemplated by the inventor of carrying out his invention (*i.e.,* the **Best Mode** requirement).

Dr. Amiji's reports did not discuss the Best Mode requirement. Thus, we must look only at his analysis of the Written Description and Enablement requirements.

1. THE WRITTEN DESCRIPTION REQUIREMENT

In his opening report, Dr. Amiji stated that "claims 1, 2, 6, and 7 are invalid for lack of adequate written description." (ECF 56-2, pg. 108 § XV.) He states, "It is my opinion that the ’802 patent specification does not reasonably convey to a person skilled in the art that the inventor was in possession of any formulation or composition that would operate in the manner claimed in the ’802 patent as of the filing date of the application." (*Id.* at ¶236.)

To support this opinion, Dr. Amiji admits that the "specification provides numerous formulations and ranges of components," but he objects to the lack of test data that would show that these formulations would work as described. However, this is not the established standard. **Evidence of testing is not required**. It is merely required that the inventor provide a disclosure of his invention. Dr. Amiji misinterprets the written description requirement of 35 U.S.C. § 112.

In the specification of the '802 Patent, the inventor, Ashok Wahi, provided ten separate embodiments showing formulations that would

function as described along with an explanation of the mechanism of operation. The composition of ingredients in the formulations is provided in ranges given in percent by weight. That means that for each disclosed embodiment, many formulations exist, which satisfy the criteria of an adequate written description. More will be explained when discussing Dr. Amiji's opinions for the enablement requirement of 35 U.S.C. § 112, It is expected that a PHOSITA who is interested in making and using the invention would need to perform some experimentation, as long as such experimentation is not undue. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d 788 (Fed. Cir. 1985).

Finally, Dr. Amiji said, "Nor is there any explanation or disclosure within the ’802 Patent that would demonstrate to a person skilled in the art that the mere fact of electrostatically inhibiting such particulate matter will be sufficient to render such particulate matter harmless." Once again, Dr. Amiji mistakes the written description requirement of § 112 for the enablement requirement.

2. THE ENABLEMENT REQUIREMENT

Dr. Amiji states his opinion that, "claims 1, 2, 6, and 7 are invalid for lack of enablement." (ECF 56-2, pg. 101, § XIV.) Dr. Amiji states:

> *The ’802 Patent also describes prior art patents addressing electrostatically charged compositions, but noting that “those*

> *compositions simply create an electrostatic field that helps to filter out oppositely charged materials" and that "[w]hile this action may offer suitable protection against particles that are inhaled passively, they suffer from the fact that they cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as microorganisms that are motile within the air stream." '802 Patent at 2:42-52.*
> (ECF 56-2, pg. 102, ¶220.)

This section must be dealt with in two parts. First, in the patent application[6] that resulted in issuance of the '802 Patent, the preamble of claim 1 originally read:

> *A method for **electrostatically preventing harmful particulate matter from infecting an individual** through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:*

And, the preamble of claim 2 originally read:

> *A formulation for **electrostatically preventing harmful particulate matter from infecting an individual** through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:*

In the '802 Patent, the only difference is that the word "preventing" in the claims is replaced by the word "inhibiting."

[6] U.S. Patent Application No. 12/467,271 filed by Ashok Wahi on May 16, 2009.

On August 25, 2011, during prosecution of the patent application, the USPTO patent examiner issued an office action, which is submitted concurrently as Exhibit A. In that office action, the examiner rejected all pending claims under 35 U.S.C. § 112, first paragraph for failing to meet the enablement requirement. (ECF 61-2, pg. 2.) This was the only rejection made by the examiner. The examiner asserted that the term "preventing" means that "not even one of the infectious material is allowed to infect, *i.e.*, pass into the system of the host." (*Id.* at pg. 3.) The examiner held:

> *In order to overcome the rejection set forth infra, it is suggested that Applicant consider amending claims 1,2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.* (*Id.* at pg. 2.)

In response, the Applicant amended the claims by changing the word "preventing" to the word "inhibiting." The claims of the '802 Patent are now bound to this amended interpretation by prosecution history estoppel. Thus, claims 1 and 2 of the '802 Patent allow for some infectious material to pass into the user's respiratory system.

In his deposition, when questioned about the above paragraph, Dr. Amiji said, "I understand what the examiner meant. I don't agree with the

examiner, but I understand what he means." (Depo. Amiji 128:15.) It must be noted that the examiner is in a position of authority, and that this matter was considered by the USPTO prior to allowing the application to issue as the '802 Patent.

The second issue to be considered is the 35 U.S.C. § 112 requirement, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, **...**" Once again, Dr. Amiji objects to the lack of test data to demonstrate that the formulations in the various formulations contained in the ten listed embodiments actually work as described. As argued *supra*, this is not a requirement of any provision in patent law.[7] As long as a PHOSITA is able to make and use the invention without undue experimentation, the enablement requirement of 35 U.S.C. § 112 is satisfied. A patent is not required to be a manufacturing specification. Some experimentation is allowed, but it must not be undue. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d. See also, *Engel Indus., Inc. v. Lockformer Co.,* 946

[7] Patents are regularly issued by the USPTO where there has been no actual reduction to practice, but rather where there has been a constructive reduction to practice. For example, a patent for a machine may be issued even if the machine had not been built prior to the application filing date.

F.2d 1528 (Fed. Cir. 1991). Efficacy testing may be performed by the PHOSITA once the formulation is duplicated.

In his report, Dr. Amiji said, "nor does the ’802 Patent provide any examples or any guidance as to how the percentages of components can be varied while still achieving 'the same results.'"

At the Markman Hearing held by this Court on November 15, 2022, much ado was made by Defendant that the ten formulation embodiments were disclosed in ranges and that there was no disclosure of a specific composition that enables the claim, and that it would take undue experimentation to develop such a specific composition. In response, Plaintiff stated that all the formulations would be effective as long as the ingredient concentrations remained within the stated ranges. Plaintiff pointed to the tenth embodiment as an example, and displayed a formula where most of the ingredient concentrations were in the midrange of those disclosed in the tenth embodiment. This formulation is shown in ECF 51-1, pg. 20. That formulation approximates the product first marketed by Plaintiff after the '802 Patent issued. Any pharmaceutical formulator who is a PHOSITA would know how to prepare this formulation using only the patent's specification as a guide.

At this point, it should be apparent that Dr. Amiji does not fully understand the written description requirement or the enablement requirements of 35 U.S.C. § 112.

D. DR. AMIJI'S OPINIONS REGARDING 35 U.S.C. § 102 AND § 103.

35 U.S.C. §§ 102, 103 deal with unpatentability of a claimed invention based upon prior art. 35 U.S.C. § 102(a)(1) states that, "a person shall be entitled to a patent unless **...** the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention **...**" 35 U.S.C. § 102(a)(1) is known as the ***anticipation statute***. A claim is anticipated, and therefore unpatentable, if **a single reference teaches every limitation of that claim**. *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 (Fed. Cir. 1987). Unless every limitation of the claim is taught by a single prior art reference, the claim is not anticipated under § 102. Further, a prior art reference that is not enabled cannot be used to anticipate a claim. *Azko N.V. v. United States ITC*, 808 F.2d 1471 (Fed. Cir. 1986).

35 U.S.C. § 103 provides that even if a claimed invention is not identically disclosed as set forth in § 102, it would still be unpatentable if it is obvious to a PHOSITA. A PHOSITA is a fictitious person technically

proficient in his art and who is familiar with all the prior art in his field. Although such a person is not an innovator, he is not an automaton either. However, he should be able to **combine a plurality of prior art references to teach every limitation of the claim**. However, unless every limitation of the claim is taught by the prior art, the claim is not obvious under § 103.[8]

In his report, Dr. Amiji provided three opinions alleging invalidity of the claims of the '802 Patent based upon prior art:

- Claims 1, 2, 6, and 7 are invalid in view of Wadstrom[5] alone or in combination with Rolf[6]. (ECF 56-2, pg. 44.)
- Claims 1, 2, 6, and 7 are invalid in view of Wahi '488[7] alone, or in combination with Rolf. (ECF 56-2. pg. 58.)
- Claims 1, 2, 6, and 7 are invalid in view of Baker '189[8] or Baker '476[9] alone, or in combination with Rolf or Khaled[10] or Rabe[11] or Katz[12] or Wahi '790[13]. (ECF 56-2, pg. 74.)

The particulars of Plaintiff's rebuttal arguments to Dr. Amiji's opinions are contained in Amirali Haidri's reply expert report (ECF 56-3). Mr. Haidri has the educational requirements sufficient to understand the technology of the '802 Patent, and even those educational requirements proffered by Dr. Amiji for his idea of a PHOSITA. Moreover, Mr. Haidri

[8] *In re. Gleave*, 560 F.3d 1331, 1332 (Fed Cir. 2009), citing *Eli Lilly & Co. v. Zenith Goldline Pharms, Inc.,* 471 F.3d 1369, 1373 (Fed. Cir. 2006); *Net Money IN, Inc. v. Verisign, Inc.* 545 F.3d 1359, 1370 (Fed. Cir. 2008); *In re. Bond,* 910 F.2d 831, 832-33 (Fed. Cir. 1990).

has had specific familiarity with the '802 Patent technology since 2018 because of his prior representation of the Plaintiff.

In his opinions *supra*, Dr. Amiji referenced the USPTOU.S. Patent Application Publication No. 2004/0071757 by David Rolf. This is a published patent application that never issued as a patent because it was held by the USPTO examiner to not be enabled under 35 U.S.C. §112. In his report (Exhibit 3, pp. 9-11), Dr. Lemmo further described the lack of enablement of the Rolf reference. Yet, Dr. Amiji used this reference to show obviousness under 35 U.S.C. § 103. A reference that is not enabled cannot be used to anticipate a patent claim.

However, the purpose of this section of the brief is to argue that Dr. Amiji misinterpreted the statutes and legal standards that deal with unpatentability based upon prior art. As argued *supra*, a claim is anticipated under 35 U.S.C. § 102 if a single prior art reference teaches every limitation of the claim. As discussed above, Dr. Amiji argued that the claims at issue are invalid in view of Wadstrom alone, in view of Wahi '488 alone, and in view of Baker '189 or Baker '476 alone. Here, Dr. Amiji refers to single prior art references, thus invoking the anticipation standard.

In Dr. Amiji's deposition at 54:2-55:21, the following question and answer session ensued:

Q: Do you understand the difference between anticipation and obviousness, then?
A: **Again, in the context of when I'm looking at it as a technical expert.**
Q: So, wouldn't you agree that for a claim to be anticipated, a single prior art reference must encompass every element in that claim?
A: **Yes. That's the standards that you apply for anticipation.**
Q: Wouldn't you also agree that for a claimto be obvious over prior art, in Section 103, a combination of prior art references must be used to encompass every element of the claim?
A: **That's my understanding. and again, for obviousness analysis, the prior art can be combined in order to then come to all the elements of the claim.**
Q: So, the combination must produce all the elements of the claim?
A: **Must provide evidence to a person of skill in the art with reasonable expectation of success.**
Q: And that is a difference between anticipation requiring a single reference that's going to do everything and a combination of references, which in other words, anticipation is all done with one -- am I correct in terms of your understanding that anticipation requires only once a single references and obviousness requires a combination of references; is that your understanding?
A: **That's generally where -- and that's the analysis that I've done, that for a claim to be invalid, it is anticipated by a single item of prior art.**
Q: Okay. So you would agree that if a single prior art reference does not encompass every element of the claim, that claim cannot be invalid over that single prior art reference alone, am I correct?
A: **Only under the anticipation argument, but it can certainly be invalid based on the obviousness argument.**

This last answer is an incorrect interpretation of the obviousness standard. A claim is neither anticipated nor obvious over a single prior art reference unless every limitation of the claim is taught in that reference.

In Defendant's Motion for summary judgment, it was presented that Baker '476 anticipates the claims at issue in the '802 Patent. This allegation is refuted by Mr. Haidri (ECF 56-3, pp. 67-68) in the section, "1. Validity Analysis Based On Baker '476 Alone." Briefly, on page 68, he states:

> *Baker '476 teaches the CATCH and KILL elements. However, like its parent application, it is silent regarding the HOLD element. Holding the harmful particles in place is a critical element in claims 1 and 2. Thus, neither claim 1 nor claim 2 of the '802 Patent is anticipated by Baker '476. Further, if claim 2 is not anticipated, then claims 6 and 7 cannot be anticipated because dependent claims 6 and 7 incorporate by reference all of the limitations of claim 2.*

As argued *supra,* in order for prior art to anticipate a claim under 35 U.S.C. §102, a single prior art reference must encompass every element of the claim. Here, this is not the case. Thus, Baker '476 cannot anticipate coams 1, 2, 6, or 7 because the HOLD element is missing.

Finally, it is difficult to ascertain the standards used by Dr. Amiji to allege invalidity of the claims at issue of the '802 Patent. He labels his section with the heading, "Anticipation and Obviousness." (ECF 56-2, pg. 44.) However, he does not say whether the claims are anticipated or obvious. He merely uses the catch-all term, "invalid." Certainly, where he proposes combining the prior art references, he alleges obviousness. However, 35 U.S.C. § 103 requires that obviousness must be determined through the lens of a PHOSITA. In his deposition, Dr. Amiji testified that

he considers himself to be a PHOSITA. (Depo. Amiji, 81:22 - 82:8.) However, Dr. Amiji is a person having extraordinary skill in the art. But, Dr. Amiji is determining obviousness of the claims through his own viewpoint. What is obvious to him is not necessarily obvious to the PHOSITA whose qualifications were already determined by this Court.

Dr. Amiji has already presented his opinions on anticipation and obviousness under 35 U.S.C. §§ 102, 103. He has neither already opined, nor is he necessarily able to opine, on the determination of obviousness of the claims of the '802 Patent at issue through the lens of the PHOSITA who was accepted by this Court.

IV. CONCLUSION

The standard for invalidating a patent is very high. A defendant's burden is not by the "more likely than not" preponderance of the evidence standard. Based on the arguments put forth herein, it is apparent the BlueWillow has not met its burden of proof by a clear and convincing evidentiary standard. If that burden has not been met, then the default status of the '802 Patent must be maintained. The claims at issue must be held as valid.

Summary judgment on the issue of patent validity is proper under Fed. R. Civ. P. 56 at this time because all of the material facts relating to this issue are already known.

For the reasons stated herein, Trutek respectfully requests that the Court enter summary judgment in its favor.

Dated: __March 29, 2023__

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 4:21-cv-10312

Hon. F. Kay Behm

CERTIFICATE OF SERVICE

Undersigned hereby states that on March 29, 2023, the attorneys for Plaintiff caused the foregoing document to be served upon all counsel of record, via electronic service.

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